

REMARKS

Reconsideration of this application is respectfully requested.

Upon entry of the foregoing amendment, claims 19-20 and 30-34 are pending in the application. Claims 19, 33 and 34 are amended.

Applicants respectfully request entry of the above amendment and submit that the above amendment does not constitute new matter.

Support for amendments to the claims can be found throughout the specification and in the claims as originally filed. In particular, support for the amendment to claim 19 can be found, *inter alia*, in the specification at page 4, lines 4 and 25-27 and in original claim 11. Support for the amendment to claim 33 can be found, *inter alia*, in original claims 8, 9 and 13. Support for the amendment to claim 34 can be found, *inter alia*, in the specification at page 4, lines 4 and 25-27 and in original claim 11.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

The Office Action states that claims 19-20 and 30-34 are rejected under 35 U.S.C. § 112, para. 2, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, the Office Action states that claims 19 and 34 are vague and indefinite on the ground that “indice” allegedly is not a word. Claims 19 and 34, as currently amended, do not contain the term “indice.” Hence, the rejection of claims 19 and 34 has been rendered moot. Accordingly, Applicants respectfully request the Examiner to withdraw the rejection of claims 19 and 34 under 35 U.S.C. § 112, para. 2.

The Office Action states that, in claim 33, the term “OE” is vague and indefinite as that term allegedly has not been defined in the specification. Applicants’ use of the term “OE,” instead of “EO,” in claim 33 was a typographical error. Claim 33, as currently amended, recites the term “EOs” instead of “OE.” Hence, the rejection of claim 33 under 35 U.S.C. § 112, para. 2, has been rendered moot.

The Office Action recognizes that “use of the term ‘EO’ has been previously addressed but the use of the term ‘OE’ has not.” Paper No. 104, page 3. The Office Action is correct in its recognition that the term “EO” has been previously addressed in the prosecution of the instant application. In particular, in the Office Action of January 23, 2003 (Paper No. 18), the Examiner withdrew all previous rejections relating to the use of the term “EO” in view of Applicants’ Response to Office Action filed November 4, 2002. Therefore, Applicants respectfully submit that claim 33, which, as currently amended, contains the term “EOs” is definite as written. Accordingly, Applicants respectfully request the Examiner to withdraw the rejection of claim 33 under 35 U.S.C. § 112, para. 2.

Furthermore, claims 19 and 34, as currently amended, also include the term “EO.” Claims 19 and 34 are amended to include the term “EOs,” to replace “ethoxylation indice,” for consistency purposes. Applicants submit, for at least the reasons stated above with respect to claim 33, that claims 19 and 34, as currently amended, fulfill the requirement of definiteness under 35 U.S.C. § 112, para. 2.

Regarding the rejection of claim 34, the Office Action states that claim 34 is “nonsensical” because

[i]n view of Applicant’s response, filed 1/7/04, it is the Examiner’s interpretation of Claims 19, 20, 30, 31, and 33 that said claims recite a method of making a vaccine comprising combining an adjuvant and an antigen. Claim 34 then recites a method of making a vaccine comprising administering said vaccine to a subject. Administering is not a method of making a vaccine.

Paper No. 104, pages 2-3. Applicants respectfully traverse this rejection.

Contrary to the position stated in the Office Action, Applicants submit that claim 34 does not recite “a method of making a vaccine comprising administering said vaccine to a subject.” *Id.* Rather, claim 34 relates to “[a] method of providing an adjuvant effect to a vaccine.” In the Remarks set forth in Applicants’ Amendment Under 37 C.F.R. § 1.116 of January 7, 2004, Applicants stated:

More specifically, the vaccine is provided with an adjuvant effect from the combination of the vaccine component with the claimed surfactants which have an overall HLB number between 5 and 15. Thus, the method which provides the adjuvant effect is the “combining” of the vaccine component (i.e. at least one antigen or at least one in vivo generator of a compound comprising an amino acid sequence) with the surfactant. Further, new claim 34 also recites the administration of the vaccine

Amendment Under 37 C.F.R. § 1.116 of January 7, 2004, page 4 (emphasis added). Accordingly, Applicants assert that claim 34 recites a method which provides the vaccine with an adjuvant effect from the combination of the vaccine component with the surfactant and which further provides the vaccine with an adjuvant effect by the administration of said vaccine to a subject. Thus, Applicants assert that claim 34 is definite as written and respectfully request the Examiner to withdraw the rejection of claim 34 under 35 U.S.C. § 112, para. 2.

Therefore, in light of the above reasons, Applicants assert that any alleged argument of indefiniteness of claims 19-20 and 30-34 has been effectively rebutted. Consequently, Applicants respectfully request that the rejection of claims 19-20 and 30-34 under 35 U.S.C. § 112, para. 2, be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

The Office Action states that claims 19-20 and 30-34 are rejected under 35 U.S.C. § 112, para. 1, because the specification allegedly does not contain a written description of the claimed invention and the disclosure allegedly does not reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed.

With regard to claims 19 and 34, the Office Action states that the term “indice” has not been found in the specification. Claims 19 and 34, as currently amended, do not contain the term

“indice.” Hence, the rejection of claims 19 and 34 has been rendered moot. Accordingly, Applicants respectfully request the Examiner to withdraw the rejection of claims 19 and 34 under 35 U.S.C. § 112, para. 1.

Regarding claim 33, the Office Action states that the term “OE” has not been found in the specification. Applicants’ use of the term “OE,” instead of “EO,” in claim 33 was a typographical error. Claim 33, as currently amended, recites the term “EOs” instead of “OE.” Hence, the rejection of claim 33 under 35 U.S.C. § 112, para. 1, has been rendered moot.

As discussed above, the Office Action recognizes that “use of the term ‘EO’ has been previously addressed but the use of the term ‘OE’ has not.” Paper No. 104, page 3. The Office Action is correct in its recognition that the term “EO” has been previously addressed in the prosecution of the instant application. In particular, in the Office Action of January 23, 2003 (Paper No. 18), the Examiner withdrew all previous rejections relating to the use of the term “EO” in view of Applicants’ Response to Office Action filed November 4, 2002. One such rejection was based on enablement on the purported ground that “EO is not defined in the specification.” *See* Office Action of December 13, 2001 (Paper No. 10), page 3. As the Examiner withdrew this rejection relating to the use of “EO” in light of Applicants’ Response of November 4, 2002, Applicants respectfully submit that the specification provides written description for claim 33, which, as currently amended, contains the term “EOs.” Accordingly, Applicants respectfully request the Examiner to withdraw the rejection of claim 33 under 35 U.S.C. § 112, para. 1.

Furthermore, claims 19 and 34, as currently amended, also include the term “EOs.” Claims 19 and 34 are amended to include the term “EOs,” to replace “ethoxylation indice,” for consistency purposes. Applicants submit, for at least the reasons stated above with respect to claim 33, that the specification provides written description for claims 19 and 34 under 35 U.S.C. § 112, para. 1.

The Office Action states that the specification and the claims as originally filed do not provide support for “[t]he method of claim 32, comprising a process for enhancing the immune response to a vaccine comprising administering said vaccine to a subject.” Paper No. 104, page 3. The Office Action further states that the specification and the claims as originally filed do not provide support for “the method of claim 34, comprising a method of providing an adjuvant effect

to a vaccine comprising administering said vaccine to a subject.” *Id.* Applicants respectfully traverse the rejection of claims 32 and 34.

The specification of the instant application states:

The composition according to the invention can be used as a preventive or curative medicinal product. Depending on the nature of the antigen or of the *in vivo* generator, *a composition according to the invention can be administered* to fish . . . to Canidae such as dogs . . . to primates, to Bovidae, to Ovidae and to horses. *The composition of the invention can also be administered to humans.* The administration of the composition can be carried out conventionally via the parenteral route, in particular by subcutaneous, intramuscular or intraperitoneal injection, or via the mucosal route

(Specification, page 8, lines 3-11) (emphasis added). Furthermore, in Example 1, the specification describes the administration of the various compositions, including compositions of the invention, to mice to determine cellular immune response. Also, the specification states that “the expression ‘*in vivo* generator of a compound comprising an amino acid sequence’ refers to an entire biological product capable of expressing said compound *in the host organism into which said in vivo generator has been introduced.*” (Specification, page 3, l. 30 to page 4, l. 1) (emphasis added). The specification further states that “[t]he concentration of said *in vivo* generator in the composition according to the invention depends, here again, in particular on the nature of said generator and of *the host in which is [sic] administered.*” (*Id.*) (emphasis added). Therefore, Applicants assert that the specification provides support for claims 32 and 34, and that the rejection of claims 32 and 34 based on lack of written description in the specification has been effectively traversed. Accordingly, Applicants request the Examiner to withdraw the rejection of claims 32 and 34 under 35 U.S.C. § 112, para. 1.

Therefore, in light of the above reasons, Applicants assert that any alleged argument of lack of written description regarding claims 19-20 and 30-34 has been effectively rebutted. Consequently, Applicants respectfully request that the rejection of claims 19-20 and 30-34 under 35 U.S.C. § 112, para. 1, be withdrawn.

CONCLUSION

Applicants respectfully request entry of the above claim amendments.

All of the stated grounds of rejection have been properly traversed, accommodated or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

In view of the above claim amendments and remarks, early notification of a favorable consideration is respectfully requested. The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-0206.

Respectfully submitted,

Dated: 8/25/04

By: Jessica L. Parezo

Robert M. Schulman
Registration No. 31,196

Jessica L. Parezo
Registration No. 50,286

HUNTON & WILLIAMS LLP
Intellectual Property Department
1900 K Street, N.W.
Suite 1200
Washington, DC 20006-1109
(202) 955-1500 (telephone)
(202) 778-2201 (facsimile)

RMS/JLP/cbt